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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,643	09/17/2003	Steven L. Smith	50563/THD/K163	5056
23363	7590	03/31/2005	EXAMINER	
CHRISTIE, PARKER & HALE, LLP			HUYNH, LOUIS K	
PO BOX 7068				
PASADENA, CA 91109-7068			ART UNIT	PAPER NUMBER
			3721	
DATE MAILED: 03/31/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/664,643

Applicant(s)

SMITH ET AL.

Examiner

Louis K. Huynh

Art Unit

3721

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's cancellation of claims 1-5 by the amendment filed 02/11/05 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6, lines 11-12; claim 12, lines 10-11, claim 20, lines 10-11: "the at least one sacrificial port attached to the front and rear sheets by a second seal *spaced apart* from the permanent seal " lacks proper antecedent basis in the specification. The second seal is a different seal that cooperates with the permanent seal to form a closed container for aseptic filling; therefore, the second seal cannot be spaced apart from the permanent seal. Applicant is respectfully requested to verify this structural limitation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 12 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Owensby et al. (US 5,324,233).

Art Unit: 3721

Owensby discloses a method for forming flexible container including the steps of: providing a front and rear sheets made of vapor impermeable transparent flexible ethylene propylene copolymer film (42) (col. 5, lines 15-45) suitable for medical solution; heating the front and rear sheets with a peripheral sealing means (31) to form permanent peripheral seals defining bottom (52) and sides (51) of a pouch (50) (col. 7, lines 59-63) while a top end (54) remains open and forms a gap for providing a channel between the front and rear sheets to receive a filling port; and providing a port (53) interposed between the front and the rear sheets and in communication with a channel in the top end of the pouch, wherein the filling port is attached to the front and rear sheets by a second seal (col. 7, line 64 – col. 8, line 13). Note that the opening in the top end (54) is sealed together, with the filling port (53) interposed between the first and second sheets, by sealing bars (10) in a port sealing means (38) and the second seal is spaced apart from the permanent seal which comprises the bottom (52) and the sides (51) of the pouch (50). Regarding the limitation of the port being “sacrificial,” the claimed method does not include any step of removing and/or destructing the port; therefore, the claimed “sacrificial port” is considered as a conventional filling or dispensing port.

With respect to Claim 20, the pouch (50) of Owensby includes two ports (53) wherein one of which is a filling port.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6-8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owensby et al. (US 5,324,233) in view of (Smith et al. (US 5,176,634).

With respect to Claim 6, Owensby discloses a method for forming flexible container including the steps of: providing a front and rear sheets made of vapor impermeable transparent flexible ethylene propylene copolymer film (42) (col. 5, lines 15-45) suitable for medical solution; heating the front and rear sheets with a peripheral sealing means (31) to form permanent peripheral seals defining bottom (52) and sides (51) of a pouch (50) (col. 7, lines 59-63) while a top end (54) remains open and forms a gap for providing a channel between the front and rear sheets to receive a filling port; and providing a port (53) interposed between the front and the rear sheets and in communication with a channel in the top end of the pouch, wherein the filling port is attached to the front and rear sheets by a second seal (col. 7, line 64 – col. 8, line 13). Note that the opening in the top end (54) is sealed together, with the filling port (53) interposed between the first and second sheets, by sealing bars (10) in a port sealing means (38) and the second seal is spaced apart from the permanent seal which comprises the bottom (52) and the sides (51) of the pouch (50).

The method of Owensby meets all of applicant's claimed subject matter but lacks the specific teaching of the front sheet comprising polypropylene-polyethylene co-polymer blended with styrene ethylene-butylene styrene elastomer. However, polypropylene-polyethylene co-polymer blended with styrene ethylene-butylene styrene elastomer is known in the art as a suitable material for forming flexible container containing medical solution and is disclosed in US 5,176,634 to Smith et al. (col. 5, lines 29-50); therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have modified the

Art Unit: 3721

method of Owensby by having provided the specific polypropylene-polyethylene co-polymer blended with styrene ethylene-butylene styrene elastomer of Smith as the material for the front sheet and/or the rear sheet since such material is well known in the art for forming flexible container containing medical solution. Regarding the limitation of the port being “sacrificial,” the claimed method does not include any step of removing and/or destructing the port; therefore, the claimed “sacrificial port” is considered as a conventional filling or dispensing port.

With respect to Claim 7, the modified method of Owensby meets all of applicant's claimed subject matter but lacks the specific teaching of a step of heating the front and rear sheets to form a peelable seal extending between two sides of the common peripheral edge and form a first and second compartments. Smith teaches that it is well known in the art that multiple medical solutions are stored in separate compartments (18, 20) on a common package such as a container (10) made of flexible material and the compartments (18, 20) of the container (10) are defined by peripheral seal (10a, 10b, 16a, 16b) and a peelable seal (24) extending between the side seals (10a & 10b) formed by heat-sealing (col. 4, lines 22-50). Therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have further modified the method of Owensby by having provided a step of forming a peelable seal extending between the side seals (51) of the pouch (50) by heat-sealing, as taught by Smith, in order to form a first and a second compartments each containing a different medical solution if so desired.

With respect to Claim 8, Smith discloses in detail the preferred material that make up the front and rear sheets of the container (10) including a layer of aluminum foil (col. 5, line 29 – col. 6, line 5). Thus, it would have been obvious to an ordinary skilled person in the art, at the

time the invention was made, to have utilized such preferred material disclosed in the Smith reference in the modified method of Owensby.

With respect to Claim 13, the method of Owensby meets all of applicant's claimed subject matter but lacks the specific teaching of a step of heating the front and rear sheets to form a peelable seal extending between two sides of the common peripheral edge and form a first and second compartments. Smith teaches that it is well known in the art that multiple medical solutions are stored in separate compartments (18, 20) on a common package such as a container (10) made of flexible material and the compartments (18, 20) of the container (10) are defined by peripheral seal (10a, 10b, 16a, 16b) and a peelable seal (24) extending between the side seals (10a & 10b) formed by heat-sealing (col. 4, lines 22-50). Therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have modified the method of Owensby by having provided a step of forming a peelable seal extending between the side seals (51) of the pouch (50) by heat-sealing, as taught by Smith, in order to form a first and a second compartments each containing a different medical solution if so desired.

8. Claims 9, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owensby et al. (US 5,324,233) in view of Smith et al. (US 5,176,634) as applied to claim 8 above ; and further in view of Larkin (US 4,608,043).

With respect to Claim 9, the modified method of Owensby meets all of applicant's claimed subject matter but lacks the specific teaching of a second sacrificial port in communication with the second compartment. Larkin discloses a flexible container (10) having two separate compartment (28 & 30) for containing liquid 42 and medicament 44, respectively,

Art Unit: 3721

and each compartment is provided with a separate port (38 & 40) for filling the container and/or administering the content from the container. Therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have further modified the method of Owensby by having provided a second port in communication with the second compartment, as taught by Larkin, so that medical solution can be filled into and/or dispensed from the second compartment of the flexible container. Regarding the limitation of the port being "sacrificial," the claimed method does not include any step of removing and/or destructing the port; therefore, the claimed "sacrificial port" is considered as a conventional filling or dispensing port.

With respect to Claim 14, the modified method of Owensby meets all of applicant's claimed subject matter but lacks the specific teaching of a second sacrificial port in communication with the second compartment. Larkin discloses a flexible container (10) having two separate compartment (28 & 30) for containing liquid 42 and medicament 44, respectively, and each compartment is provided with a separate port (38 & 40) for filling the container and/or administering the content from the container. Therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have further modified the method of Owensby by having provided a second port in communication with the second compartment, as taught by Larkin, so that medical solution can be filled into and/or dispensed from the second compartment of the flexible container. Regarding the limitation of the port being "sacrificial," the claimed method does not include any step of removing and/or destructing the port; therefore, the claimed "sacrificial port" is considered as a conventional filling or dispensing port.

Art Unit: 3721

With respect to Claim 15, Owensby further teaches that the pouches can be filled before or after the ports are seals the pouches (col. 8, lines 26-33). It would have been obvious to a person in the art to have understood that medical solution must be filled through the ports in the case the pouches are to be filled after the ports had been sealed to the pouches. Furthermore, aseptically filling is known in art of filling medical solution into flexible pouches; for example: Barney (US 5,462,526) discloses a method of aseptically filling medical solution into flexible pouches (col. 3, lines 2-11); therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have aseptically filled the pouches through the ports.

Response to Arguments

Applicant's arguments filed 02/11/2005 have been fully considered but they are not persuasive.

Applicant contends that the reference to Owensby does not disclose a gap that exists concurrently with the permanent seal. Applicant is respectfully directed to the Owensby reference at col. 7, line 58 – col. 8, line 13), which states:

“In practice the flexible film web 42 having two layers of films is fed into a peripheral sealing means 31, by a feeding means (not shown). The peripheral sealing means makes the seals which define the sides and bottom edges of the flexible film pouches. These pouches still having an open top end are then transferred, by a transfer means 32 to a cutting means 33... Next the indexing means 37 moves the flexible film pouches with inserted fitment tubes to port sealing means 38 where the sealing of the fitment tubes and the open top end of the pouches is accomplished using sealing means 10 (not shown).”

It is clear from the passage that the pouch of Owensby is provided with a gap in the top end (54) for receiving the fitment tubes (53) and the fitment tubes are then sealed to the pouch by

the port sealing means (38) which is different from the peripheral sealing means (31). Thus, claim 12 and the new claim 20 are fully anticipated by Owensby.

Similarly, a prima-facie of obvious has been reasonably set forth in rejecting claim 6 and the dependent claims 7-9 and 13-15.

Allowable Subject Matter

9. Claims 10, 11 and 16-19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

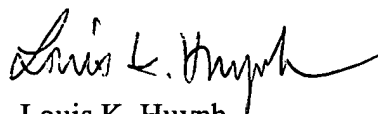
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is (571) 272-4462. The examiner can normally be reached on M-F from 9:30AM to 5:00PM.

Art Unit: 3721

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (571) 272-4467. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Louis K. Huynh
PRIMARY EXAMINER
Art Unit 3721

March 24, 2005